

DEC 9 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICIAL

In re application of: IZHAR

Confirmation Number: 8900

Application No.: 09/411,863

Group Art Unit: 1638

Filing Date: October 4, 1999

Examiner: A. Kubelik

For: EXOGENIC ALLELISM

Attorney Docket No.: 85189-4300

DECLARATION OF DR. VERED YESODI UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Vered Yesodi, declare that:

1. I am a citizen of Israel and reside at 54 Irusim Street, Reut, ISRAEL.
2. I hold a Ph.D. in Genetics from The Hebrew University of Jerusalem, a M.Sc. degree from Tel-Aviv University, Faculty of Life Sciences, and a B.Sc. from Ben-Gurion University, Department of Biochemistry.
3. I am presently CEO of Fertiseeds Ltd. Prior to this I was the Research Director of In-Vitro Fertilization (IVF) Laboratory, Racine IVF Unit at LIS Maternity Hospital in Tel-Aviv. I also did a Post doctorate at Tel-Aviv University, Medical School, Department of Embryology and was a research assistant at Volcani Center for Agricultural Research in the Department of Virology for 2 years. I have published nine scientific articles in highly regarded journals and books.
4. I have reviewed and I understand the above-identified patent application, the full file and presently amended claims and the Office Actions, in particular the Examiner's rejections under 35 U.S.C. §102(e) and §103(a) as being unpatentable over U.S. Patent No. 6,392,119 to Gutterson *et al.* (referred to hereafter as "Gutterson"). I am making the following statements as one of ordinary skill in the art in support of the patentability of the presently amended claims.

5. The above-identified application is directed to methods of generating exogenic allelism in a plant and to the plants and plant seeds produced by these methods. Specifically, as set forth in amended claim 47, the specification discloses a method of generating a male sterile plant characterized by exogenic allelism, which involves the step of actively selecting progeny devoid of a polynucleotide encoding exogenic recombinase prior to the final step of crossing this progeny with the second plant. This step is important in order to provide stability to the plants produced by the disclosed method.

6. As one skilled in the art, based on my review of the application, the office actions, and Gutterson, it is my opinion and judgment that the method as set forth in amended claim 47 is not anticipated or made obvious by Gutterson.

7. After reviewing Gutterson, I conclude that Gutterson fails to teach the active step of selecting "a progeny devoid of the polynucleotide sequence encoding said recombinase." Furthermore, Gutterson does not even suggest that any modifications are warranted to his disclosed process, providing no motivation to modify his process, especially by adding an additional step of "selecting progeny devoid of the polynucleotide sequence encoding recombinase."

8. Selecting for progeny devoid of the polynucleotide that encodes recombinase is an active step that is important to the stability of plants generated by our method which are characterized by exogenic allelism. This step is an additional active step as compared to the process Gutterson teaches. Furthermore, this step is different than the step Gutterson teaches of selfing and select for homozygosity--a step typically done in the greenhouse, using traditional breeding techniques. Our step requires that after selfing in the greenhouse, we bring the progeny from the greenhouse into the laboratory, which can be time consuming and sometimes expensive, but which is very important in order to provide stable exogenic allelism in the offspring which will be characterized by exogenic allelism. The laboratory work involves molecular biology techniques, such as, Southern Blot and PCR analysis, *etc.*

9. In view of the importance of this step, providing stable exogenic allelism in the plants produced, and the fact that this step is an active step that is time

consuming and relatively expensive, it would seem to me that if the prior art knew about the importance and value of this additional step of selecting out the recombinase gene, one skilled in the art would expect there to be some teaching or at least suggestion in the prior art that such a step should be performed.

10. In addition, in view of the rejection over Gutterson, I searched the literature extensively based on the Examiner's obviousness concern. I did not find any prior art in the form of a report, paper, patent, *etc.* in this field that recommend or advise selecting for plants devoid of recombinase.

11. Based on the foregoing, it is thus my opinion and judgment, as one of skill in the art, that Gutterson does not make the method of claim 47, specifically the step of selecting progeny devoid of the polynucleotide encoding recombinase, obvious to one skilled in the art. One skilled in the art would not be motivated to modify the Gutterson method to add the additional active step of selecting for progeny devoid of recombinase.

12. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated: Dec. 9 2003

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Vered Yesodi, Ph.D.

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DECLARATION OF DR. EZRA YAGIL UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Ezra Yagil, declare that:

1. I am a citizen of Israel and reside at 15 Hecharuv St., Ramat-Hasharon, ISRAEL.
2. I hold a Ph.D. in Genetics from the University of California, Davis CA, USA and a B.Sc. Degree in Agriculture from the Hebrew University, Jerusalem, ISRAEL.
3. I am presently a Professor of Genetics in the Dept. of Biochemistry, Tel-Aviv University, ISRAEL. I have published 58 peer-reviewed scientific papers several of them in the field of site-specific recombination and edited two books. I spent 3 sabbatical years, two of which at the National Inst. of Health in Bethesda MD, USA and one at the University of Oregon in laboratories whose expertise is in genetic recombination.
4. I have reviewed and I understand the above-identified patent application and the presently pending claims. I am making the following statements as one of ordinary skill in the art in support of the patentability of the pending claims.
5. I provide this declaration to declare and set forth my opinion as one skilled in the art that I believe that the step of selecting progeny devoid of a polynucleotide sequence encoding a recombinase is not an obvious step in the presently claimed invention, but that it significantly contributes to stability of the exogenic allelism generated.

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6. I also declare that I have no financial interest in Fertiseeds, Ltd.

7. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated: Dec. 9, 2003

Ezra Yagil
Ezra Yagil, Ph.D.

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Examiner: A. Kubelik

For: EXOGENIC ALLELISM

Attorney Docket No.: 85189-4300

DECLARATION OF DR. NIR OHAD UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Nir Ohad, declare that:

1. I am a citizen of ISRAEL and reside at 10 Moshe Kol St. Jerusalem
ISRAEL
2. I hold a Ph.D. in Genetics from The Hebrew University of Jerusalem, a
M.Sc. degree in genetics, from The Hebrew University of Jerusalem, and a B.Sc from The
Hebrew University of Jerusalem.
3. I am presently employed as lecturer at the Department of Plant
Sciences in Tel-Aviv University engaged in both teaching and as a PI supervising graduate
students working in my laboratory studying plant embryogenesis. I was trained in the field of
plant embryogenesis as a postdoctoral fellow in the Department of Plant Biology at U.C
Berkeley for 5 years.
I have published sixteen articles in highly regarded journals.
4. I have reviewed and I understand the above-identified patent
application and the presently pending claims. I am making the following statements as one of
ordinary skill in the art in support of the patentability of the pending claims.

5. I provide this declaration to declare and set forth my opinion as one skilled in the art that I believe that the step of selecting progeny devoid of a polynucleotide sequence encoding a recombinase is not an obvious step in the presently claimed invention, but that it significantly contributes to stability of the exogenic allolism generated.

6. I also declare that I have no financial interest in Fertiseeds, Ltd.

7. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated: 9-12-2003

Nir Ohad
Nir Ohad, Ph.D.